UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

In re: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	) MDL No. 2545) Master Docket Case No. 1:14-cv-01748) Honorable Matthew F. Kennelly
This Document Relates To: *Edwin Clay Harris v. AbbVie Inc.et al.* Case No. 1:14-cv-07963	)

PLAINTIFF'S LOCAL RULE 56.1 RESPONSE TO DEFENDANTS' STATEMENT OF FACTS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGEMENT AS TO ALL OF PLAINTIFF HARRIS' CLAIMS AND MOTION TO EXCLUDE GENERAL AND CASE-SPECIFIC EXPERTS

Plaintiff Colonel (ret.) Edwin Harris' ("Col. Harris" or "Plaintiff"), through undersigned counsel and pursuant to Local Rule 56.1, provide the following response to Defendant's Statement of Material Facts in Support of Their Motion for Summary Judgement as to all of Plaintiff's claims and motions to exclude general and case-specific experts:

1. Undisputed.

2. Disputed as to the assertion Abbot specializes in medical devices, diagnostic equipment, and nutrition products" as unsupported by the cited evidence (Doc. 1), which states: "At all relevant times herein, Abbott Laboratories, Inc. was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including AndroGel in the states of Georgia and Illinois." Otherwise, undisputed.

3. Undisputed.

4. Undisputed that Plaintiff does not recall using AndroGel in 2004. Disputed as to the suggestion that his deposition was the first time he did not recall this. Col. Harris has no

recollection of his 2004 prescription, or using AndroGel in or around 2004, and has never suggested otherwise in this litigation. (See Ex. 1, Nov. 11, 2014 PFS pgs. 14-15 (served Dec. 29, 2014))

5. Undisputed.

6. Disputed in part. Dr. Futral's medical records do not state that Col. Harris was diagnosed with primary hypogonadism. And Dr. Futral testified that he did not diagnosis Col. Harris with hypogonadism based on any disease listed on the 2011 label. Instead, Dr. Futral based his diagnosis on what Dr. Futral referred to as the "most common reason" which is "testicular failure due to aging." (Ex. 2, Futral Dep. 62:2-63:17) AndroGel has never been indicated for age-related hypogonadism and was intended to be used only for classical hypogonadism. (Ex. 3, AbbVie-FST00503741) Undisputed that Plaintiff initiated the request for AndroGel.

7. Undisputed that Dr. Futral prescribed AndroGel in August 2012 and that pharmacy records show Plaintiff filled 30-day supplies in August and October. That pharmacy records also indicate that Col. Harris filled a 30-day supply for AndroGel prescribed by Dr. Futral in September 2012. (Ex. 4, EHA_0008-9)

8. Disputed. Dr. Futral's records show lab work for Col. Harris dating back to at least January 10, 2012, where Dr. Futral noted a PSA was performed showing that Col. Harris's PSA was 6.30 ng/ml. (Ex. 5, EHA_00078.) Those records also include PSA levels on February 1, 2012; February 3, 2012; February 14, 2012; and, August 14, 2012. (*Id.*, at EHA_00080-84, 86, 92, 95-96) Undisputed, however, that there is **no record of a blood test showing low testosterone**. *See id.* Col. Harris also disputes Defendants' characterization of Dr. Futral's testimony and the factual inference Defendants draw that lab results exist. Dr. Futral testified that it was his "practice" to "find out what the testosterone level is" but, he did not testify that such labs were done for Col. Harris prior to prescribing him AndroGel. (Ex. 2, Futral Dep. 91:7-9) ("I don't see it in his records; so I hope that wasn't something that was missed.") Medicare records show labs performed in 2012,

but no labs testing Col. Harris's testosterone levels. Ex. 6, HARRISE-86CMMS-0077 at 00079-80) Moreover, Dr. Futral's records do show lab work with testosterone levels done on Col. Harris in 2013—long after Col. Harris had stopped taking AndroGel and suffered his stroke—and they were within normal range. (Ex. 2, Futral Dep. 91:10-11) Col. Harris also disputes that he had primary hypogonadism. Again, Defendants misquote the testimony. Dr. Ehret testified that he did *not* diagnose Col. Harris with hypogonadism in 2012:

> Q Did you diagnose him with those?
> A The erectile dysfunction, ***but the hypogonadism, no***. That was 2012.

(Ex. 7, Ehret Dep. 167:4-10 (emphasis added)) Dr. Ehret testified that he *assumed* Col. Harris had hypogonadism in 2012 because Dr. Ehret had previously diagnosed Col. Harris with low testosterone in 2004. (*Id.* at 167:13-16) But the evidence undermines Dr. Ehret's assumption. In September 2013—long after Col. Harris was off AndroGel—Col. Harris's testosterone levels were normal. (Ex. 5, at EHA_000103; Ex. 2, Futral Dep. 91:10-92:11)

9. Undisputed that the language Defendants quote is in the AndroGel label that was in effect in 2012, but the actual evidence Defendants have cited is the 2002 label, which was not in effect in 2012.

10. Undisputed that Dr. Futral was previously aware of the need to check hematocrit and he is still unclear about whether TRT helps or hurts, but otherwise disputed. Dr. Futral actually testified, "cardiovascular risk, not – not directly no, I wasn't aware of that." (Ex. 2, Futral Dep. 143:8-145:17) According to Dr. Futral he only monitored hematocrit every 6 months which would not have prevented Col. Harris' stroke. (*See* Ex. 2, Futral Dep. 93:16-18) Moreover, Dr. Futral did not consider the label's suggestion to monitor hematocrit levels sufficient to trigger a warning of heart attack or stroke. (*See* Ex. 2, Futral Dep. 144:19-145:17 (testifying that what "was unique was the studies that came out [with] a possible direct association with cardiovascular disease. You

understand the difference [between that and high hematocrit levels]? One was something that we would infer based on what knowledge we had of those conditions and one was—was a direct result of the application … One is a secondary and one's a primary.")) In contrast, after 2015, Dr. Futral began warning all of his patients that TRT potentially causes cardiovascular events, including stroke, when the FDA issued its safety precaution advising doctors of the adverse studies. (*Id.* at 52:15-59:17). And the information added to the 2015 label is "the type of information that led [him] to start warning [his] patients … that there is a possible increase risk of stroke … before they take AndroGel." (*Id.* at 64:16-65:13) ("Yes.") (*See also* Ex. 2, Futral Dep. 64:2-65:13; 143:21-144:7; 188:23-189:23)

11. Disputed that Col. Harris was diagnosed with primary hypogonadism as defined by the 2011 label and disputed that Dr. Ehret testified that he discussed the increase of cardiovascular risks with Col. Harris. Dr. Ehret's medical records do not say "primary hypogonadism." (Ex. 8, Ehret Dep. Ex. 3 at p.3; Ex. 9, Ehret Dep. Ex. 6 at EHA_00468) Dr. Ehret testified that Col. Harris had hypogonadism not in conjunction with any other disease as required for an on-label prescription, but merely because he had low testosterone levels on *one* test. (Ex. 7, Ehret Dep. 48:14-21; Ex. 8, Ehret Dep. Ex. 3 at 1 (initiating AndroGel on Sept. 14, 2004); Ex. 10, Ehret Dep. Ex. 4 at 1) Moreover, the evidence is that Col. Harris did not have primary hypogonadism because his testosterone levels were in the normal range without medication in 2013. (*See supra* ¶ 8) Disputed that Dr. Ehret discussed the risk of heart attack or stroke with Col. Harris. Dr. Ehret testified "always we discuss the possible elevation of hemoglobin and hematocrit, the possible – watch for DVT, BPH, increased PSA. Those are the ones I routinely go over with the patients when we start this, things to look for, and then what we monitor for." (Ex. 7, Ehret Dep. 21:4-9) Dr. Ehret testified that he does not have in the records what risks he would have discussed with Harris, but confirms it would have been consistent with the risk information that was available at

the time and he would not have discussed the risk of stroke with Col. Harris. (Ex. 7, Ehret Dep. 139:24-140:22)

12. Undisputed that Dr. Ehret and Dr. Futral discussed risks with Col. Harris that were known to them in 2012, but disputed that the risks included heart attack and stroke. Dr. Futral and Dr. Ehret testified they would not have warned Col. Harris about the risk of heart attack or stroke in 2012. (Ex. 2, Futral Dep. 59:1-12; Ex. 7, Ehret Dep. 139:24-140:22) The reason Col. Harris inquired about risks with Dr. Ehret in 2012, even though Dr. Ehret did not prescribe AndroGel, was find out of it was safe for him given his BPH. (*Id.* at 115:1-11; Ex. 9, EHA_00467-68).

13. Disputed. Dr. Futral looks at the label for the risks and benefits of the drug. (Ex. 2, Futral Dep. 134:24-135:6 ("You said that you . . . would look at the labels for certain – I guess you said risks and benefits? . . . A: Yeah. . . . Mostly the risks will be reviewed.")) Dr. Futral also testified that he does rely on the pharmaceutical manufacturer to disclose the risks (*id.* at 22:3-23:2), and he reviews "Dear Doctor" letters, particularly ones that "disclosed a serious risk like heart attack or stroke." (*Id.* at 24:24-25:6) Dr. Futral also attended seminars that are commonly sponsored by the pharmaceutical companies for information about the risks and benefits of a drug, and obtained summaries of the drug's labels from these seminars. (*Id.* at 23:8-24.2; 27:2-9)

14. Irrelevant since Dr. Ehret did not prescribe AndroGel to Col. Harris in 2012. But nonetheless disputed. Dr. Ehret testified that he relies on more than his own independent training and experience, including sources like the physicians' desk reference, or UpToDate, or he'll "just go pull up the package insert from the—directly from the manufacturer." (Ex. 7, Ehret Dep. 36:14-37:23) He also testified any information from Defendants about the true risks would have been taken into account when determining how to treat a patient. (*Id.* at 149:6-20)

15. Undisputed, although irrelevant.

16. Undisputed that Dr. Futral so testified but Dr. Futral also learned during the deposition that he is not aware of all risks, such as that that gel-based products like AndroGel actually increase estradiol levels. (Ex. 2, Futral Dep. 179:20-181:12) Dr. Futral stated he would have liked to have additional information about that risk. (*Id.* at 179:2-180:13; 183:18-184:5) Dr. Futral also testified that about half of the patients he prescribes TRT to stop treatment within six months because they do not see any benefits. (*Id.* at 103:19-105:4)

17. Irrelevant because Dr. Futral is not being offered as a general causation expert; Disputed in part. Prior to August 2012, Dr. Futral was never warned that that AndroGel could cause cardiovascular disease; even today it is "unclear" to him. (*Id.* at 188:23-189:6) (When asked whether he would still prescribe AndroGel to Col. Harris knowing what he knows now about the risks, Dr. Futral answered "I'm not sure whether I would or not. It depends on his complaints and – it may still be worth the risk depending on the benefit.") "[A]t minimum, [he would have] warned him about the stroke" if he knew in 2012 what he knows today. (*Id.* at 189:8-13) ("Yes.")

18. Undisputed that Col. Harris first learned of AndroGel when he saw advertisements, but he did not recall that he first started taking it in 2004. Plaintiff has had trouble recalling past events since his stroke. (Ex. 11, Harris Dep. 240:15-241:23)

19. Disputed. Col. Harris did not have primary hypogonadism. (*Supra* ¶ 6; 8) Moreover, Dr. Ehret did not remember an initial prescribing discussion with Col. Harris, and was merely guessing about how it would have gone. (Ex. 7, Ehret Dep. 71:6-24 ("Q: Do you know how the discussion with AndroGel came about in this time period of 2004? Is that something that you suggested to him to take AndroGel, or he raised it with you? The specific drug. A. **No.** I don't **think** he mentioned the drug by name, no.") (emphasis added))

20. Disputed. Col. Harris did not state he exclusively relied upon his doctors. (Ex. 11, Harris Dep. 221:1-223:24) He testified that he would not have taken AndroGel if he had been

warned about the risk of stroke. (*Id.* at 293:6-10) Further, at the time of these questions, Col. Harris was wholly unaware that AbbVie employs sales representatives who are not doctors whose job it is to influence a doctor's prescribing decisions. (*Id.* at 291:4-13 ("I had no idea that this was going on.")) He also did not know that AbbVie had specifically targeted, his doctor, Dr. Futral. (*Id.* at 291:23-292:6 ("Somebody ought to be prosecuted…"))

21. Disputed. The only evidence Defendants cite is Dr. Ehret's deposition, and Dr. Ehret did not prescribe AndroGel to Col. Harris in 2012. Moreover, Dr. Ehret's 2004 diagnosis is likely wrong for the reasons indicated above. (*See supra* ¶¶ 6, 8 9, 11, 19) And there is no evidence that Dr. Futral was aware of or relied on Dr. Ehret's (mistaken) 2004 diagnosis.

22. Undisputed.

23. Disputed. The evidence Defendants cite concerns Plaintiff Edward Natale, not Col. Edwin Harris. With respect to Col. Harris, Dr. Ziman acknowledged that Col. Harris may have had elevated plaque levels at the time of his stroke but there is no way to know based on the evidence at this time. (Ex. 12, Ziman Dep. 338:18-339:17)

24. Disputed. The document Defendants cite for the suggestion that Col. Harris had full blown LVH provides merely that "Mild LVH is present." (Ex. 13, HARRISE-59EACHD-00239 at 240) More importantly, the same document notes that "left ventricle is normal size" and that "Echocardiogram showing normal [left ventricle] size and systolic function." (*Id.*)

25. Disputed. Col. Harris' hypertension was adequately controlled for the most part. (Def. Ex. C at 21 ("has a history of long-standing hypertension that in my opinion was adequately controlled, for the most part, in the years leading up to his stroke"); Ex. 12, Ziman Dep. 330:29-331:22) Defendants cite to a medical record that references an isolated incident in which Plaintiff's primary care physician was unable to bring the hypertension under control but a specialist was able

to do so. (Ex. 12, Ziman Dep. 331:9-22) Defendants' citation to Plaintiffs' Amended Fact Sheet confirms his hypertension is "treated and under control." (Defs. Ex. G at 9)

26. Undisputed.

27. Disputed. Dr. Ziman's report specifically addresses the CT scan Defendants cite here and concludes that the lacunar infarct diagnosis is "a spurious artifact and is not correct." (Def. Ex. C at 20) Dr. Ziman notes that CT scans are "not sensitive enough to detect the subtler features" of strokes, and that "subsequent imaging, including MRI imaging, has not confirmed the lacune that is noted on his initial head CT." (*Id.*) In addition, Dr. Hazariwala, Col. Harris' treating neurologist in 2012 (Ex. 14, Hazariwala Dep. 5:10-6:4), definitively testified that based on the MRI imaging and her treatment of Col. Harris, Col. Harris had no prior stroke. (*Id.* at 103:11-105:8)

28. Undisputed.

29. Disputed. Col. Harris' stroke occurred on October 15, 2012, but his hematocrit level was not taken until October 20, 2012, five days after he stopped using AndroGel. (Ex. 15, HARRISE-41PNH-00076; Ex. 11, Harris Dep. 234:18-235:24) Moreover, Dr. Ziman has testified that Plaintiff's hematocrit and homgolobin levels, while within the "normal" range for the population at large, nevertheless were elevated for this Col. Harris and contributed to Col. Harris' stroke. (Ex. 12, Ziman Dep. 342:3-18)

30. Undisputed that these tests are not routinely done, but Dr. Ziman provides evidence that AndroGel increases platlet activity and thromboxane A2 receptor density and so a reasonable juror could infer that Col. Harris suffered from these issues. (Def. Ex. D at. 18, 27, 29, 31, 52)

31. Undisputed that estradiol levels are not routinely tested, but Dr. Ziman provides evidence that AndroGel increases estradiol levels so a reasonable juror could infer that Col. Harris suffered an increase. (Def. Ex. D at 18-19, 25-27, 31-32, 46, 52-53)

PLAINTIFF'S STATEMENT OF ADDITIONAL MATERIAL FACTS

1. Based on the representations in Defendants' advertisements, Col. Harris asked Dr. Futral to prescribe him AndroGel in 2012. (Ex. 11, Harris Dep. 27:16-31:8; Ex. 16, Plaintiff Fact Sheet, p. 15)

2. Dr. Futral uses "shared decision making" between him and the patient, to determine whether to prescribe a drug and the patient makes the ultimate decision to use the drug. (*See* Ex. 2, Futral Dep. 40:16-41:6)

3. Defendants identified Dr. Futral as an "AndroGel Target M.D" and sales representatives called on him ten times from June 2011 to December 2011. (*See* Ex. 2, Futral Dep. 27:15-29:10, 38:12-39:2; 39:9-40:9, 181:22-182:2; Ex. 17, Futral Dep. Ex. 2025)

4. Defendants provided Dr. Futral with the HIM Study to show the purported prevalence of untreated hypogonadal males. (Ex. 2, Futral Dep. 33:22-34:3; Ex. 18, Futral Dep. Ex. 2015) They also provided marketing materials and prescription coupons. (Ex. 2, Futral Dep. 31:8-32:21)

5. Prior to 2012, Defendants' sales representatives called on Dr. Futral extensively. (Ex. 18, Dep Ex. 2015) They sold him on the use of AndroGel to treat depression, the "viagra story," erectile dysfunction, and "reminded [him] to screen all patients when presented with signs or symptoms of depression, fatigue and sexual dysfunction." (Ex. 2, Futral Dep. 29:13-30:8; 37:12-19; Ex. 18, Futral Dep. Ex. 2015) When he prescribed AndroGel to Col. Harris, although Dr. Futral noted no blood test showing low testosterone, he noted that patient reports: "difficulty attaining erection," "libidio is low," "low energy levels, depression, weakness and weight gain," (Ex. 5, Dep. Ex. 2026 at EHA_00096), the same symptoms pushed by Defendants' sales representatives.

6. Dr. Futral testified that, at the time he prescribed AndroGel to Col. Harris in 2012, he wanted laboratory evidence proving that Col. Harris had low testosterone before prescribing

AndroGel. (Ex. 2, Futral Dep. 94:18-24) But there is no laboratory evidence that Dr. Futral measured Col. Harris's testosterone levels, nor evidence that he had low testosterone in 2012. Nor is there over evidence that Col. Harris was suffering from primary hypogonadism, or any other legitimate disease that decreases testosterone levels, prior to prescribing AndroGel to Col. Harris.

7. In October 2012, two months after he started AndroGel, Col. Harris suffered a left posterior temporal lobe thrombotic ischemic stroke. (Def. Ex. C at 23)

8. Dr. Ronald B. Ziman, a board certified neurologist, reviewed the relevant records, performed a differential etiology, and determined, "to a reasonable degree of medical certainty and to a medical probability," that "AndroGel was a substantial factor in the etiology of his stroke and its sequela," and that "but for Col. Harris's use of AndroGel, he would not have experienced a thrombotic ischemic stroke." (Def. Ex. C at 23)

9. Col. Harris stopped using AndroGel after his stroke in 2012. He has not suffered another stroke, nor has he had any other cardiovascular events. (*See* Ex. 16, Plaintiff Fact Sheet p. 11; Def. Ex. C at 21)

10. Dr. Futral could not warn Col. Harris that AndroGel may cause a stroke, because Defendants had not disclosed the potential risk to him in 2012. (Ex. 2, Futral Dep. 65:2:13) Dr. Futral did start warning patients about the potential risk of stroke and heart attack when the FDA required AbbVie to change the label in 2015. (Ex. 2, Futral Dep 58:16-59:11)

11. Dr. Futral agrees that in 2012, he would have wanted to know if Defendants were aware or could have been aware that AndroGel increased the risk of a stroke. (Ex. 2, Futral Dep. 41:18-24)

12. Between 2000 and 2015, FDA repeatedly told Defendants that TRT products were not approved for "age-related" hypogonadism, andropause, or low testosterone levels due to aging. In 2000, FDA Review Officer Mark Askine warned that "Claims and representation that suggest

AndroGel is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." (Ex. 19, Kessler Ref. 101) On July 22, 2002, as reported in an article in *The New Yorker* magazine, FDA Director of Division of Reproductive and Urologic Drug Products Dr. Daniel Shames stated that "the F.D.A. never approved AndroGel for andropause. We're not sure what 'andropause' is. The intention was that AndroGel would be for people with conditions like Klinefelter's and pituitary dysfunction." (Ex. 20, ABBVIE-00315440 at ABBVIE-00315457) On February 9, 2004, Dr. Shames repeated these concerns in a PBS broadcast, stating "I don't know what the treatment is treating, I don't know if andropause really exists at all." He concluded, "[W]e're very concerned here about the use of this product in this age group, especially when we never intended it for it to be used for this purpose." (Ex. 21, ABBVIE-00043639 at ABBVIE-00043641 and ABBVIE-00043643)

13. Colonel Harris was never warned about the risk of heart attack or stroke by Defendants, Dr. Futral, or Dr. Ehret. (Ex. 11, Harris Dep. 293:6-22) If he had been warned, he never would have requested the AndroGel prescription and never would have taken it. (*Id.* at 204:8-13, 293:1-22)

14. From at least 2000 through 2013, Defendants spent hundreds of millions of dollars on an aggressive campaign to directly convince consumers to buy AndroGel, and to directly convince physicians to prescribe it for men with age-related hypogonadism, or "Low-T." (*See* Ex. 22-28) As early as 1999 Unimed and Solvay's marketing department recognized the possibility of significant market expansion if men could be persuaded to talk to their doctors about testosterone therapy possibly causing symptoms such as fatigue, decreased libido, and body changes such as weight gain. (Ex. 22, Kessler Ref. 158-60) A 2001 "Strategic Concept" reflected the intention to increase the use of AndroGel from 150,000 men in 2000 to 3-4 million men by 2001-2002, and then further increase the market by direct-to-patient/consumer advertising after 2002. (Ex. 23, Kessler Report at 57) Defendants began direct to consumer advertisements through unbranded websites, third parties, and

television advertisements encouraging aging men to request that their healthcare professionals test them for "Low-T." (Ex. 24, Kessler Ref. 234) The 2003 AndroGel Business Plan included selling messages to use with health care professionals included "more than 1 in 10 of your male patients 50-59 may have low testosterone" and that testosterone screening should become routine for males over 40 even for males without clinical symptoms. (Ex. 25, Kessler Ref. 176) Defendants conducted extensive education campaigns on andropause and age-related hypogonadism, suggesting that physicians routinely test for "Low-T" and represented that "Low-T" or Andropause are medical conditions that need treatment as opposed to normal decline in testosterone over time. (Ex. 23, Kessler ¶¶ 225, 384, 405-427; *Id.* at ¶¶ 207-218) Defendants provided "diagnostic questionnaires" that were so vague as to diagnose almost any healthy aging male as having symptoms of testosterone deficiency. (Ex. 23, Kessler ¶ 306) Defendants spent 91.5 million in promotion and advertising in 2011 and planned to spend 105.4 million in 2012. (Ex. 26, ABBVIE-FST02652627 at ABBVIE-FST02652637) Defendants utilized sales representatives that were assigned particular doctors to call upon during office hours and to arrange out of office dinners and presentations. (Ex. 27, Hill Dep. 44:13-45:25, 114:4-18) AndroGel sales representatives were trained with modules where hypogonadism was often called "Low-T." (*Id.* at 67:18-24) AndroGel sales representatives received incentive compensation based on the number of AndroGel prescriptions written within their territory. (*Id.* at. 24:20-25:5; 28:17-29:4; 30:23-31:3) AndroGel was marketed and sold to treat "Low-T" by AndroGel sales representatives. (Ex. 28, Dixon Dep. 40:3-7)

15. There is no evidence in the record that Defendant AbbVie maintains a place of business in Georgia.

16. There is no evidence in the record that Defendant Abbott maintains a place of business in Georgia.

17. There is no evidence in the record that Defendant AbbVie keeps assets within Georgia.

18. There is no evidence in the record that Defendant Abbott keeps assets within Georgia.

Dated: July 12, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 11, 2018, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Bradley T. Wilders
Bradley T. Wilders